

UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

Friday, December 07, 2012

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 7313-EA
DP Barcode: DP 407299
Product Name: Sigma X075

From: Ian Blackwell, Biologist *IB*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader *IB for KPH*
Chemistry and Toxicology Team *12/7/2013*
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell/Demson Fuller
Regulatory Branch 1
Antimicrobials Division (7510P)

Applicant: PPG Architectural Finishes, Inc.,

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt</u>
119093	2-(p-Chloridephenyl)-3-cyano-4-bromo-5-trifluoromethylpyrrole	5.42
128101	4,5-Dichloro-2-n-octyl-4-isothiazolin	5.23
	<u>Other Ingredient(s):</u>	<u>89.35</u>
	Total:	100.00

I BACKGROUND:

1. PPG Architectural Finishes submitted a request for the waiver of the acute inhalation toxicity requirement (OCSPP Guideline 870.1300). After six attempts of trying to aerosol the product, the laboratory conducting the study concluded that the study could not be performed per the guideline methodology.
2. The company did not perform product-specific testing for the other five acute toxicity studies. Instead, the company cited studies that were previously submitted to support the product, Sigma Nexxium 20 (EPA Reg. No. 7313-23, formerly EPA Reg. No. 83353-5). PPG Architectural Finishes believes that the two formulations are substantially similar
3. A data matrix listing the following acute toxicity studies and proposed toxicity categories is cited below:

Study	MRID Number	Toxicity Category
Acute Oral Toxicity	456732-02	III
Acute Dermal Toxicity	456732-03	IV
Acute Inhalation Toxicity	None	
Primary Eye Irritation	456732-04	II
Primary Skin Irritation	456732-05	III
Dermal Sensitization	456732-06	Yes

II RECOMMENDATIONS:

1. The agency waives the acute inhalation toxicity requirement for File Symbol 7313-EA. EPA agrees with the rationale that if the product cannot be aerosolized during laboratory testing, it will not be possible to conduct an acute inhalation toxicity study. In accordance with this waiver, the proposed product will be assigned toxicity category IV for acute inhalation toxicity.
2. The agency does not believe that the formulation of File Symbol 7313-EA is substantially similar to the Sigma Nexxium 20 product. PPG Architectural Finishes is proposing to bridge up to a more toxic/irritating concentration. The company believes that the higher active ingredient percentage in the proposed product will be offset by lower levels of inerts, thus the toxicity of the overall product are lower in concentration to EPA Reg. No. 7313-23. The Agency is

concerned with the differences of active ingredients in the two products. In the absence of data, the agency cannot determine if this bridging justification is sound. A higher percentage of the active ingredient might affect the toxicity of any or all of the acute toxicity requirements. Therefore, EPA the company must either have new studies conducted on 7313-EA or submit studies on another product that is substantially similar to the Sigma Nexxium 20 product.

3. The agency accepts the bridging argument for the dermal sensitization study. EPA Reg. No. 7313-23 contains 4,5-Dichloro-2-n-octyl-4-isothiazolin. The isothiazolin class tends to be dermal sensitizers

The acute toxicity profile for File Symbol 7313-EA is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity			Data Gap
Acute Dermal Toxicity			Data Gap
Acute Inhalation Toxicity	None	IV	Waived
Primary Eye Irritation			Data Gap
Primary Skin Irritation			Data Gap
Dermal Sensitization	456732-06	Sensitizer	Acceptable

III LABELING:

1. The Signal Word cannot be determined until the acute toxicity profile is adequately complete.
2. No Precautionary Statements or First Aid Statements can be recommended until the company properly addresses the product's data gaps.